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November 18, 2019

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: In re Valsartan NDMA Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

Pursuant to the Court's October 22, 2019 Order (Dkt. 280), the Manufacturing Defendants[1] submit this letter brief in response to Plaintiffs' letter brief on the following "macro" discovery issues: (1) whether Defendants' alleged 'boilerplate' objections should be summarily overruled and deemed waived; (2) which of Defendants' entities and/or manufacturing facilities must respond to Plaintiffs' discovery; (3) whether Defendants should be required to identify and produce discovery

[1] The positions expressed in this letter are those of the Manufacturing Defendants to whom the Plaintiffs' discovery requests have been directed. Because the retailers (the "Retailer Defendants") and the wholesaler/distributor/repackaging defendants (the "Wholesaler/Distributor/Repackaging Defendants") have not been involved in the meet and confers relating to these issues, and consistent with the Court's November 7, 2019 Order (Dkt. 292) that Plaintiffs serve any Wholesaler/Distributor/Repackaging or Retailer specific document requests by November 26, the Retailer Defendants and the Wholesaler/Distributor/Repackaging Defendants reserve the right to comment at a later date on these issues. For these reasons, references to "Defendants" throughout this letter brief refer to the Manufacturing Defendants only.

regarding other products using the same manufacturing processes, solvents, and/or testing as those for valsartan API; and (4) the extent of discovery regarding Defendants' litigation holds.

I. PRELIMINARY STATEMENT

Plaintiffs in this case seek discovery with virtually no limit. They seek over a decade's worth of documents related to valsartan sold anywhere in the world, through 248 sweeping document requests (including all sub-requests), to be searched for with over 400 search terms and modifiers, from the custodial files of *hundreds* of custodians. They now argue, with little factual support, for unlimited discovery into every facility and entity that ever touched valsartan and into *at least four other drugs*. They make no attempt—whether through their document requests, their approach to ESI searching, or their positions in these letter briefs—to adhere to their obligation to use discovery tools "to secure the just, speedy, and inexpensive determination" of these actions. Fed. R. Civ. P. 1. As the federal judicial system has recognized for over twenty-five years, attorneys must not "attempt to use discovery tools as tactical weapons" that will "result[] in excessively costly and time-consuming activities that are disproportionate" to the needs of the case. 1983 Advisory Committee Notes to Rule 26.

But that is the inescapable conclusion from Plaintiffs' request for unbounded discovery into all facilities, all entities, an unidentified number of drugs, and Defendants' litigation holds. Plaintiffs offer little to no support for these requests, which will dramatically expand the scope of discovery and serve only to increase costs and delay the discovery process.[2] The Court should reject Plaintiffs' attempt to convert discovery in this MDL into a costly, unmanageable morass, and instead "focus discovery…on what is truly necessary to resolve the case." *Chief Justice's 2015 Year-End Report on the Federal Judiciary*.[3]

II. "MACRO" DISCOVERY ISSUES

A. Defendants are serving amended objections that comply with Rule 34(b)(2)(B).

Plaintiffs' brief focuses on Defendants' original objections to Plaintiffs' document requests (Dkt. 289 at 1-6). Those arguments are now moot. After meeting and conferring to gain a better understanding of what Plaintiffs are actually targeting in their sweeping 122 document requests, Defendants have served amended objections that state their objections with additional specificity

[2] This is not to mention Plaintiffs' continued request to strike all of Defendants' objections, notwithstanding the significant time the parties have invested in good-faith efforts to confer on the scope and relevance of the document requests, which have resulted in detailed amended objections. *See* Dkt. 297 (letter explaining Plaintiffs' intent to argue that both the amended objections and original objections must be stricken).

[3] Accessible at https://www.supremecourt.gov/publicinfo/year-end/2015year-endreport.pdf (last visited Nov. 18, 2019).

and also contain responses, many of which incorporate compromises proposed on the meet and confers. This "issue" has been resolved.

1. Procedural Background

Pursuant to Case Management Order No. 12 (Dkt. 185), Plaintiffs served their First Set of Requests for Production of Documents to All API and Finished Dose Manufacturing Defendants (the "Requests") on August 31, 2019, and Defendants served their objections on October 15, 2019. By the Court's orders, Defendants were required to serve "only their objections to the document requests" by that date, not any responses. Dkt. 141, ¶ 2; *see also* Aug. 14, 2019 Tr. at 63:1–65:5 (setting 45-day deadline for objections because "we're not talking about responses," only "objections"). Because Defendants were not required to serve responses by October 15, Defendants did not identify documents that they would produce or withhold on the basis of their objections. Instead, Defendants stated throughout that many of their objections could be resolved through meeting and conferring on the scope and ambiguity of Plaintiffs' Requests.

Plaintiffs challenged Defendants' objections as boilerplate in their identification of "macro" discovery issues (Dkt. 278 at 2), and the Court ordered briefing on that issue (Dkt. 280 at 2). On November 4, 2019, the Parties met and conferred on all "macro" discovery issues, including Defendants' objections. As a result of that meeting, Defendants agreed to serve amended objections. *See* Dkt. 289 at 3 n.3. The parties then held a series of meet and confers on Plaintiffs' Requests and Defendants' objections. These meet and confers have assisted Defendants in understanding the intended scope of Plaintiffs' Requests, which has aided Defendants in explaining their objections to Plaintiffs and in formulating more specific, amended objections. Defendants served their amended objections on Plaintiffs today, November 18 ("Amended Objections").[4] *See* Dkt. 297 (letter to court on amended objections). Defendants' Amended Objections also contain responses where appropriate, even though the Court has not ordered Defendants to respond, based on discussions with Plaintiffs about the scope of their Requests.[5]

2. Defendants' Amended Objections Fully Comply with Rule 34

Rule 34(b)(2)(B) requires responding parties to "state with specificity the grounds for objecting to the request, including the reasons." The "requirement of specificity in objections should

[4] Defendants' Amended Objections omit all General Objections except for those that apply to all of the Requests. This is consistent with current best practices. *See*, *e.g.*, The Sedona Conference Federal Rule of Civil Procedure 34(b)(2) Primer: Practice Pointers for Responding to Discovery Requests, 19 Sedona Conf. J. 447, 472 (2018) ("General objections should be used only if the objections apply to all the document requests or are expressly incorporated by reference in the sub-set of requests to which they are being asserted to avoid repeating the objection. […] [T]he reason for the objection must still be specified in order to facilitate a meaningful discovery conference.").

[5] A copy of ZHP's amended objections is provided as an example. *See* Exhibit A.

be interpreted in a realistic sense." Wright & Miller, Fed. Practice & Procedure § 2213 (3d ed.). Because the goal of this rule is to "facilitate an informed discussion of the objection," courts assess the sufficiency of an objection by asking whether it provides adequate context for the parties and the court to understand what is being objected to and for what reason. 2015 Advisory Committee Notes to Rule 34; *see also, e.g., Younes v. 7-Eleven, Inc.*, 312 F.R.D. 692, 704 (D.N.J. 2015) (faulting "non-specific objections" because they are "almost impossible to assess on their merits"); *Fischer v. Forrest*, No. 14-1304, 2017 WL 773694, at *3 (S.D.N.Y. Feb. 28, 2017) (faulting objections as "boilerplate" because the "language tells the Court nothing").

Defendants' Amended Objections clearly meet this standard. For example, ZHP's Amended Objections generally read as follows:

> ZHP objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the Actions, in that it seeks "all" documents and "any modifications thereto" related to all machines, materials, and substances involved in all aspects of the Valsartan API manufacturing process, when the Master Complaints allege that the NDMA or NDEA was the result of a specific step in the manufacturing process. *See* Personal Injury Master Complaint ¶ 167; Economic Loss Master Complaint ¶ 327; Medical Monitoring Master Complaint ¶ 289 (alleging that NDMA and NDEA are byproducts of the chemical reaction involving the solvent used to create the tetrazole ring found in Valsartan API). ZHP's manufacturing process for Valsartan API involves 6 steps, with a total of 48 sub-steps. *See* PRINSTON00000606–626. Therefore, responding to this Request as written would cause ZHP to search for, review, and produce voluminous documents that are not relevant to Plaintiffs' claims, in that the Request is not limited to the machines, materials, and substances used during the specific step in the Valsartan API manufacturing process that allegedly resulted in the occurrence of NDMA or NDEA. ZHP further objects to this Request as vague, overbroad and unduly burdensome, lacking in particularity, and unreasonable, as "all documents with regard to the machines, materials, and substances" does not identify any particular set of documents and is duplicative of other Requests, including Requests No. 21 and 25. ZHP further objects to this Request as it is unlimited in time and requests information about the manufacturing process that predates November 27, 2011, the date on which ZHP initiated the manufacturing process change that resulted in the manufacturing process for all Valsartan API sold into the United States. *See* PRINSTON00074768.
>
> Notwithstanding the above, during a meet and confer on November 8, 2019, Plaintiffs indicated that this Request is intended to be more narrow than its drafting suggests, and thus, as memorialized in a letter from Plaintiffs dated November 11, the Parties agreed at the meet and confer that, upon the production of certain documents by ZHP set forth as follows, Plaintiffs will endeavor to narrow this Request should Plaintiffs seek the production of additional documents responsive thereto. Accordingly, subject to the objections asserted herein, and to the parties'

> agreement reached during that meet and confer, ZHP will endeavor to produce (1) the Valsartan-related exhibits referenced in the EIRs produced during core discovery, and (2) documents and summaries described in Plaintiffs' letter dated November 11, 2019. This agreement is without prejudice to Plaintiffs' ability to seek more detailed discovery related to the particular manufacturing processes and steps they determine are material to the Actions, and without prejudice to ZHP's ability to raise objections to the scope of Plaintiffs' future requests, which ZHP will endeavor to resolve through additional meet and confers.

See Exhibit A, ZHP's Response to Request No. 20.[6]

In contrast, the objections rejected as "boilerplate" in recent cases provide no detail, which prevents a meaningful discovery conference on what is being objected to and why. For example, in *Fischer*, the Defendant objected as follows:

> Defendant objects to this Request for Production to the extent that it is overly broad and unduly burdensome, and not likely to lead to the discovery of relevant evidence. Defendant further objects to this Request as it requests information already in Plaintiff's possession.

Fischer, 2017 WL 773694, at *2. Similarly, in *Douglas*, the Defendant in stated only that:

> In response to Request Number 12, Defendant incorporates by reference all General Objections set forth above. Defendant further objects to this Request on the grounds that: (a) it seeks information that is neither relevant nor reasonably calculated to lead to the discovery of admissible evidence; and (b) it calls for documents and/or communications protected by attorney-client privilege or work product privilege.

Douglas v. Kohl's Dep't Stores, Inc., No. 15-1185, 2016 WL 1588651, at *1 (M.D. Fla. Apr. 20, 2016).

Clearly, Defendants' Amended Objections are a far cry from the "familiar litany" of the old boilerplate objections that courts now reject. Defendants have provided the reasons for their objections and detailed factual context supporting those reasons. *See NE Technologies, Inc. v. Evolving Sys., Inc.*, No. 06-6061, 2008 WL 4277668, at *5 (D.N.J. Sept. 12, 2008) (finding objections sufficiently specific when defendant "state[d]…in its brief, the reason why it would be burdensome, including the need to find and review a 'voluminous number of records at great expense,'" and that the documents were not relevant); *cf. Douglas*, 2016 WL 1588651, at *2

[6] Even Defendants' less detailed objections specify the reason for the objection as required under Rule 34(b)(2)(B). *See, e.g.*, Exhibit A at 83–84, ZHP's Response to Request No. 107 (objecting to scope of Plaintiffs' Request No. 107 related to sales information).

(faulting objections that "do not explain why the requests are irrelevant, overbroad, or otherwise objectionable"). Plaintiffs' macro discovery issue regarding Defendants' objections is now moot.

3. Defendants' Original Objections Complied with the Court's Order

Plaintiffs' suggestion that Defendants' Original Objections were somehow sanctionable, Dkt. 289 at 6, is baseless. As noted above, the Court ordered Defendants to serve "only their objections to the document requests," not any responses. Dkt. 141, ¶ 2; Aug. 14, 2019 Tr. at 63:1–65:5 (setting 45-day deadline for objections because "we're not talking about responses," only "objections"). That is exactly what Defendants did: they served objections, not responses (and therefore did not identify documents that they would produce or withhold on the basis of their objections). Instead, Defendants stated throughout that many of their objections could be resolved through meeting and conferring on the scope and ambiguity of Plaintiffs' Requests, which has now been accomplished.[7]

Furthermore, Defendants' objections must be assessed in the context of Plaintiffs' sweeping and often ambiguous document requests. Without knowing with specificity what the requests are seeking, it is nearly impossible to object with a high degree of specificity. If the propounding party does not place the responding party "upon reasonable notice of what is called for and what is not," the responding party should not have to "ponder and to speculate in order to decide what is and what is not responsive." *Lopez v. Don Herring Ltd.*, 327 F.R.D. 567, 575 (N.D. Tex. 2018) (quotations omitted).

Many of Plaintiffs' 122 document requests—not counting the numerous sub-requests—fail to satisfy this standard. Despite having more than 200,000 pages of core discovery describing, in detail, the Defendants' manufacturing processes, types of testing performed, specifications for that testing, and the FDA's investigation, Plaintiffs have made ambiguous and often duplicative requests that seek to capture every last document that references valsartan. For example, Plaintiffs have requested "all testing" ever performed or "that was considered but not performed" at any time on valsartan. *See* Dkt. 290-2 at 10 ¶ 44. During meet and confers, Plaintiffs stated that they have not yet determined which tests are relevant to detection of NDMA or NDEA, despite having thousands of pages describing a broad range of testing performed on valsartan, including FDA inspection

[7] In addition, most of the Manufacturing Defendants' objections overlap with the macro discovery issues, namely: (1) the extent of discovery regarding foreign regulatory materials and communications; (2) the extent of discovery regarding foreign sales, marketing, and agreements; (3) the extent of discovery regarding each applicable defendant's finished dose manufacturing process; (4) the extent of discovery regarding valsartan testing; (5) whether health risk discovery should be limited to the injuries alleged in the master and other complaints; (6) the relevant time period for the custodial search and production of responsive documents as to each defendant. It simply makes no sense for Plaintiffs to argue that the Defendants did not identify their objections with sufficient specificity, when the parties are exchanging extensive briefs on those very topics.

documentation and communications regarding tests performed on valsartan samples by the Defendants and the agency itself. Similarly, Plaintiffs have requested *all* drafts and *all* final versions of "policies, procedures, standard operating procedures, or protocols for or relevant to" sixteen undefined and extraordinarily broad categories:

> (1) manufacture, (2) testing, (3) purity and contamination, (4) quality assurance, (5) risk assessment, (6) medical and clinical assessments, (7) safety, (8) communications with regulatory agencies, (9) formulation, (10) production, (11) distribution, (12) packaging, (13) evaluation, (14) sale, (15) marketing, and (16) communications with private individuals or entities, with regard to valsartan, and/or the ingredients thereof.

See Dkt. 290-2 at 5 ¶ 5. Plaintiffs could not explain the contours of these categories or explain why all of them were relevant, instead claiming that they are unable to define or narrow their requests without first understanding the full scope of documents in Defendants' possession. These are only two examples from the many overly broad requests.

Plaintiffs' approach ignores the Court's explicitly stated purpose of core discovery, which was to provide Plaintiffs with the key documents that would allow them to serve focused document requests. *See* April 10, 2019 Tr. at 31:15-17 (stating that purpose of core discovery is to "guide your discovery in the case so you don't go down a rabbit hole"). Plaintiffs have apparently made little effort to use these highly relevant documents to tailor discovery. And even if core discovery did not provide Plaintiffs with sufficient information to allow them to identify specific areas of inquiry, it "is no answer for attorneys' serving … all-encompassing or broad and undirected requests for production to say that they are not certain what the responding party has in its possession, custody, or control and do not want to miss anything—and so will ask for, effectively, everything." *Lopez*, 327 F.R.D. at 577.[8]

Defendants complied with the Court's order regarding objections, and in light of Plaintiffs' facially overbroad and ambiguous document requests, objected with the degree of specificity that was possible in order to facilitate productive meet and confers, which ultimately resolved many disputes and allowed Defendants to craft their more specific Amended Objections.

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[8] In contrast to their document requests, during the meet-and-confer process Plaintiffs' counsel sent the Manufacturing Defendants a letter identifying a number of specific categories of documents responsive to their Requests. *See* Dkt. 296 at 2 n.1 (referencing Plaintiffs' letter); Dkt. 298-2 (attaching a copy of Plaintiffs' letter). Their letter betrays the obvious: Plaintiffs could have, and should have, used the information they received through Core Discovery to draft narrower and more focused document requests. Instead, Plaintiffs chose to serve facially overbroad and inappropriate document requests designed to capture every last document that could possibly relate to valsartan in any way.

B. Discovery should be limited to facilities that manufactured recalled valsartan API, and the scope of discovery into entities other than the Manufacturer Defendants should be determined after Plaintiffs serve them with document requests.

In pursuing discovery, a party is not allowed "to roam in shadow zones of relevancy[.]" *In re Fontaine*, 402 F. Supp. 1219, 1221 (E.D.N.Y. 1975). "Discovery is not intended as a fishing expedition[.] [T]he plaintiff must have some basis in fact for the action." *Claude P. Bamberger Int'l, Inc. v. Rohm & Haas Co.*, No. 96-1041, 1998 WL 684263, at *2 (D.N.J. Apr. 1, 1998) (citation and alteration omitted); *accord Hashem v. Hunterdon Cty.*, No. 15-8585, 2017 WL 2215122, at *2 (D.N.J. May 18, 2017) ("[W]hile the scope of discovery is broad, it is not unlimited and should not serve as a fishing expedition.") (internal citation and punctuation omitted).

1. Valsartan API Manufacturers

Defendants have already produced documents from their facilities that manufactured valsartan API that were subject to recalls. This should be all Plaintiffs need, since there is no dispute that the nitrosamine impurities were introduced during the API manufacturing process. Plaintiffs, however, now seek discovery from *all* facilities that manufactured valsartan API, including those API facilities that manufactured valsartan API without any impurity and not subject to any recall. In other words, it is already known and undisputed how the impurity came to exist in Defendants' API (in a particular step in the manufacturing process). Plaintiffs do not need to compare the facilities/manufacturing processes/testing methods/maintenance processes of the facilities subject to recalls and those not subject to recalls to "discover" this. Plaintiffs have no support for their argument that limiting the scope of discovery to the facilities involved in producing the effected API (*i.e.*, the relevant facilities), is "simply unacceptable." Dkt. 289 at 7.

2. Downstream Entities[9]

Plaintiffs also seek discovery of finished-dose manufacturing facilities and other downstream facilities, including those that labeled, bottled, or repackaged valsartan. *See* Dkt. 289

[9] Despite Plaintiffs' assertions in their brief, the Teva Defendants do not take the position that only one of the two finished dose manufacturing facilities is a proper subject of discovery. *See* Dkt. 289 at 9, 12-13. This is not and has never been the position of the Teva Defendants, as Plaintiffs' counsel has been told on multiple occasions. The referenced statement from counsel as to Arrow Pharm (Malta) Ltd. was included solely to note that the entity no longer exists and was not served in any underlying case prior to merging into another entity. The Teva Defendants are not "carving out" the Malta facility from discovery, and counsel for the Teva Defendants has styled their discovery responses specifically to include Arrow Pharm (Malta) Ltd. and make clear that the Teva Defendants are also responding on behalf of this former corporate entity. The Teva Defendants will produce

at 8-15. It is premature to decide the scope of any discovery geared towards downstream entities. Plaintiffs have not even served any of the distributors, wholesalers, repackagers, or retailers with document requests. Plaintiffs argue for discovery related to these entities in a vacuum. They do not specify exactly what type of discovery they believe is relevant. The Court has warned Plaintiffs, however, that they must "sharpen their pencils" and serve document requests that are not nearly as burdensome as those served on the Manufacturing Defendants. At the very least, therefore, the Court should defer its decision on the scope of discovery directed at the downstream entities until after those Defendants serve their objections and have an opportunity to be heard on the burden, proportionality, and relevance of Plaintiffs' forthcoming requests.

Plaintiffs' argument in their brief, however, does not justify any demand for discovery from the downstream entities. Their main argument for seeking this discovery seems to be that finished-dose manufacturers and other downstream facilities have their own independent regulatory and testing requirements pursuant to the Drug Supply Chain Security Act and/or current Good Manufacturing Practices ("cGMPs"). This fails, for multiple reasons.

First, the Master Complaints do not state claims for violations of the Drug Supply Chain Security Act, which makes sense, given that it does not contain a private right of action. In addition, the Master Complaints do not allege that any downstream entity failed to comply with cGMPs. And even if compliance with those authorities was relevant to the actual causes of action, Plaintiffs do not even cite a specific statutory obligation to support their argument for broad discovery into these entities. Instead, they cite generally to the entire Drug Supply Chain Security Act ("DSCSA"), 21 U.S.C. § 351 *et seq*., and to a PowerPoint presentation defining a "suspect and illegitimate product," without any further explanation. *See* Dkt. 289 at 8.

An actual reading of the DSCSA shows that it does not impose any obligation that is relevant to the identification of nitrosamines. The DSCSA establishes requirements for product identification and tracing, including the requirement that downstream entities monitor the security and reliability of their supply chain for potential counterfeit, diverted, or stolen products. 21 U.S.C. § 360eee-1(c)–(e) (establishing requirements for repackagers, wholesale distributors, and dispensers); *see also* 21 U.S.C. § 360eee(8), (21) (defining "illegitimate" and "suspect" products). As summarized in recent FDA guidance on complying with the DSCSA, downstream entities must monitor for signs that products may be from an illegitimate source, such as a trading partner that is "reluctant to provide a transaction history associated with the product," a product offered at "a price that is 'too good to be true,'" a package "that exhibits unusual or excessive adhesive residue," or a "[f]inished dosage form that seems suspicious (e.g., it has a different shape or color from an FDA-approved product, a different or unusual imprint, [or] an unusual odor….)." U.S. Food & Drug Administration, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*

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documents and respond to discovery related to the Malta facility as appropriate, subject to resolution of the specific discovery objections and macro discovery issues which may apply.

Guidance for Industry, at 8-9 (Dec. 2016).[10] Plaintiffs have proffered no argument or evidence that the downstream entities failed to comply with these obligations, and monitoring for those types of warning signals about supply chain integrity or visible product defects would not have notified any of the downstream entities that valsartan API potentially contained trace amounts of NDMA or NDEA.

Second, any valsartan API that contained NDMA or NDEA was already contaminated by the time it reached the finished-dose facilities—or, for that matter, any other "downstream" facility. And there were simply no testing procedures that could quantify or detect nitrosamine impurities at such trace amounts until the FDA introduced new testing procedures in June 2018. *See e.g.*, January 25, 2019 FDA Statement ("One challenge we've faced is that NDMA's properties make it hard to detect in standard laboratory testing – the kind of testing results that are reviewed during a surveillance inspection. In St. Louis, the FDA maintains one of the most advanced pharmaceutical laboratories of any regulatory agency in the world....[FDA's] scientists have developed and refined novel and sophisticated testing methods specifically designed to detect and quantify the NDMA and NDEA in all ARB medicines.").[11] Recognizing that the purported nitrosamine impurity was introduced during the API manufacturing process, Plaintiffs have failed to make any threshold showing of relevancy, *see Jesberg v. Baxter Healthcare Corp.*, No. 97-1062, 2005 WL 8164570, at *4 (D. Minn. June 24, 2005). At bottom, the alleged impurity found in Defendants' valsartan is traced to a discrete step in the API manufacturing process. Accordingly, Defendants are willing to engage in discovery regarding API testing and manufacturing, and the like, but finished-dose testing—and anything further downstream—is simply irrelevant.

Plaintiffs also attempt to rely on a letter from Mylan's counsel to justify discovery of finished-dose and downstream facilities, and in doing so, mischaracterize the language and the substance of the letter. On August 7, 2019, Mylan's counsel sent a letter to Plaintiffs' Co-Lead and Liaison Counsel regarding their purported deficiencies with Mylan's Core Discovery production. *See* Dkt. 289, Ex. 13. In that letter, Mylan' counsel made clear that it was not required to produce documents related to finished-dose facilities during core discovery. *See id*. That was true then, and it is true now. The fact of the matter is that discovery of finished-dose and downstream facilities

[10] Accessible at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-supply-chain-security-act-implementation-identification-suspect-product-and-notification (last visited Nov. 18, 2019).

[11] FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root cause of the safety issues, U.S. Food & Drug Administration (Jan. 25, 2019), accessible at https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps (last visited Nov. 13, 2019).

was not part of core discovery and it is irrelevant. Now that core discovery is complete—or nearly complete—Plaintiffs are not entitled to irrelevant discovery.

C. Discovery into other drugs made with similar manufacturing processes or solvents is premature, overly burdensome, and not proportional to the needs of this litigation.

These actions are about valsartan API—specifically whether, how, and why NDMA or NDEA were formed during the manufacturing process for valsartan API. The Manufacturer Defendants have already produced more than 200,000 pages of documents providing answers to those questions. Through the DMFs and ANDAs, Plaintiffs possess detailed information about the API manufacturing processes, including the raw materials, sources of raw materials, and testing done on raw materials; the chemistry behind the route of synthesis; flowcharts diagramming the dozens of steps in the manufacturing process; descriptions of all in-process testing and control measures; descriptions of the types of testing done on valsartan API; and the documents validating the effectiveness and parameters of that testing. Through the FDA communications, Plaintiffs also have reports documenting inspections of the facilities at issue, root cause analyses for the impurities, descriptions and key documents demonstrating the manufacturing process changes at issue, and pre- and post-recall chromatography test results for hundreds—if not thousands—of batches of valsartan API.

Despite already having this core information—and despite serving more than 120 sweeping document requests specific to valsartan—Plaintiffs now argue (despite never arguing for this before the Court's framing of macro discovery issues) that they also require unbounded discovery into the manufacturing processes and testing of at least four additional angiotensin II receptor blockers ("ARBs"): losartan, irbesartan, olmesartan, and candesartan. Such a dramatic expansion of discovery is not warranted. Losartan, irbesartan, olmesartan, and candesartan are irrelevant to this case, which is only about valsartan API. This expansion of discovery will also overly burden Defendants with the additional collection and review of a high volume of irrelevant and duplicative documents. This burden greatly outweighs any small benefit that Plaintiffs might gain from this additional discovery.

Moreover, as the Court is aware, there is currently a motion pending before the Judicial Panel on Multidistrict Litigation to expand this MDL to include losartan, irbesartan, and other ARBs—a demonstration that this MDL currently does *not* include those drugs. If the JPML decides to expand this MDL, only then will discovery regarding losartan and irbesartan, and potentially other ARB drugs, become relevant. Unless and until the JPML decides to expand this MDL, the issues are currently limited to the alleged NDMA and NDEA impurities in valsartan, and the relevance of other ARBs is nonexistent.[12]

[12] And even if the pending motion before the JPML were granted, discovery from certain Defendants—including Mylan and any other similarly situated Defendant who has not had any

Finally, if the Court finds that discovery into drugs other than valsartan is warranted, then it is premature to determine the scope of that discovery. Plaintiffs have served only a single document request seeking information related to drugs other than valsartan. Staging discovery by focusing on valsartan would also allow the parties to identify the specific manufacturing processes, chemical structures, and testing procedures that form the crux of this case. Discovery into drugs other than valsartan—if appropriate at all—should be limited at this time to those specific, clearly defined areas of inquiry.

1. Discovery into other drugs is not proportional to the needs of this litigation.

Discovery "is not unlimited . . . and should not serve as a fishing expedition." *Hashem v. Hunterdon Cty.*, No. 15-8585, 2017 WL 2215122, at *2 (D.N.J. May 18, 2017) (quoting *Saller v. QVC, Inc.*, No. 15-2279, 2016 WL 8716270, at *5 (E.D. Pa. June 24, 2016)). Discovery requests must be "proportional to the needs of the case, considering the … importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). "The purpose of this rule of proportionality is to guard against redundant or disproportionate discovery[.]" *Ramirez v. World Mission Soc'y Church of God*, No. 14-1708, 2019 WL 1569819, at *3 (D.N.J. April 10. 2019) (quoting *Takacs v. Union Cty.*, No. 08-711, 2009 WL 3048471, at *1 (D.N.J. Sept. 23, 2009)). Under this rule, courts "must … prevent use of discovery to wage a war of attrition or as a device to coerce a party, whether financially weak or affluent." Fed. R. Civ. P. 26 Advisory Committee Notes (2015). The "enormous expense of discovery" can "push cost-conscious defendants to settle even anemic cases," and courts must protect against this abuse of the discovery process. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 559-60 (2007) (quoting *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 347 (2005)).[13]

Discovery into other drugs is not important to resolution of the issues in this litigation (or to Plaintiffs). Exemplifying this fact, ***Plaintiffs did not even seek this discovery*** until the Court entered the order on macro discovery briefing. Despite now claiming that they "seek discovery of" the "manufacturing processes, solvents, and testing" that Defendants used for other ARBs and other drugs using unidentified solvents, *see* Dkt. 289 at 15, ***not one of Plaintiffs' requests for production asks for that information***. And Plaintiffs did not even raise discovery into other drugs as one of their macro discovery issues, instead raising only the "[i]dentification of other products." *See* Dkt. 270 at 2. Only after the Court's rewording of Plaintiffs' macro discovery issue have Plaintiffs proposed full discovery into the manufacturing processes and testing used on other drugs. In other words, in Plaintiffs' ***own framing*** of their discovery requests and macro issues, they did not seek

involvement in litigation involving losartan and/or irbesartan—would still be irrelevant and improper.

[13] The Supreme Court's concern about the coercive effect of broad discovery is particularly applicable here, where Defendants have not been permitted to narrow the scope of the claims against them through Rule 12 motions.

the information they now claim that they need—a clear indication that extensive discovery into other drugs is not necessary and unquestionably disproportionate. Furthermore, as explained above, Plaintiffs already have obtained significant, key information about the manufacturing process for valsartan through the ANDAs, DMF, and FDA inspection reports and correspondence produced before Rule 34 discovery has even begun. Rule 34 discovery will, no doubt, provide extensive additional information about valsartan. Plaintiffs have not shown what, if anything, discovery into other ARBs will uncover that discovery into valsartan will not.

By comparison, discovery into the manufacturing processes and testing for at least four other ARBs would, by definition, at least quadruple the Defendants' expense in this litigation, not to mention the expansion that would result from discovery regarding solvents used in other manufacturing processes. This would not only dramatically increase the costs of collection, attorney review, processing, and storage, it would also lead to an unmanageable discovery undertaking that will weigh these actions down with sideshows and delay upon delay. This case would become a discovery quagmire. Defendants have already produced over 200,000 pages in this MDL, the vast majority of which comprise the ANDAs and DMFs for valsartan. Adding four additional ARBs and an undetermined number of drugs using similar solvents would mean that over a million pages will likely be produced in ANDAs and DFMs alone. In short, sweeping discovery into other drugs constitutes a "disproportionate burden when weighed against slight probative value." *Gonzales v. Goodyear Tire and Rubber Co.*, No. 05-941, 2006 WL 7290047, at *7 (D.N.M. Aug. 10, 2006) (denying discovery into development, design, testing, manufacture and distribution of multiple models of tire as "clearly too broad a scope, as it would include information irrelevant to the design and manufacturing process for the subject tire and would entail excessive burden and expense to Goodyear with little or no benefit to the litigation").

2. Plaintiffs have failed to establish even a threshold showing of relevance of other drugs to justify their apparently boundless request for discovery.

Contrary to Plaintiffs' assertion, courts do not "routinely" permit discovery of other products not alleged to have caused the injury at issue. *See* Dkt. 289 at 15. Instead, "courts have undertaken a fact specific determination of the extent of the similarities or dissimilarities" of the products, "and have inquired about the basis for the discovery request." *Hofer v. Mack Trucks, Inc.*, 981 F.2d 377, 381 (8th Cir. 1992) (affirming denial of "burdensome" discovery into "the design minutiae" of truck model other than the one alleged to harm plaintiff).

Courts take a hard look at such discovery requests, requiring the requesting party to make a "threshold evidentiary showing of those other products' relevance to the product that is the subject of the dispute." *Horner v. Cummings*, No. 14-639, 2015 WL 13613261, at *2 (M.D. Pa. Oct. 27, 2015) (citing *Fine v. Facet Aerospace Prods. Co.*, 133 F.R.D. 439, 442–43 (S.D.N.Y. 1990)). The party seeking discovery of other products "bears the burden of establishing that the different products are substantially similar." *Stone v. Zimmer, Inc.*, No. 09-80252, 2010 WL 11602738, at *2 (S.D. Fla. Jan. 7, 2010) (quotation omitted). "The movant must make a specific factual showing of substantial similarity . . . ***conclusory statements of alleged similarity are not enough***." *Id.* (emphasis

supplied) (quoting *Gibson v. Ford Motor Co.*, 510 F. Supp. 2d 1116, 1120 (N.D. Ga. 2007)). Comparing models that are not substantially similar is "truly the equivalent of comparing apples and oranges." *Id.* (citation omitted). "Typically, the movant provides an expert affidavit to support its claim that the products are substantially similar." *Id.; see also Tolstih v. L.G. Electronics, USA, Inc.*, No. 07-582, 2009 WL 439564, at *1 (S.D. Ohio Feb. 20, 2009); *Barcenas v. Ford Motor Co.*, No. 03-04644, 2004 WL 2827249, at *4–5 (N.D. Cal. Dec. 9, 2004); *Piacenti v. Gen. Motors Corp.*, 173 F.R.D. 221, 223 (N.D. Ill. 1997). Plaintiffs fail to establish the relevance of other products here, and discovery into drugs other than valsartan should therefore not be permitted.

Plaintiffs' brief belies the irrelevance of discovery relating to other drugs. Although Plaintiffs dedicate ten pages to the supposed relevance of discovery into other drugs, they identify only one specific area of inquiry: whether Defendants were on notice of a nitrosamine impurity in another drug with a similar chemical structure before the July 2018 valsartan recall. *See* Dkt. 289 at 16, 20. To the extent *any* information about other drugs may be relevant to the presence of NDMA or NDEA in *valsartan*, that information would be very narrow. Plaintiffs' initial Rule 34 document requests recognize this point; the *only* request that Plaintiffs did not expressly limit to valsartan is Request No. 46, which asks for documents "with regard to any nitrosamine compound" in "valsartan or any other API." *See* Dkt. 290-2 at 11, ¶ 46. Beyond possible discovery into Defendants' potential knowledge of a nitrosamine in another drug with a similar chemical structure to valsartan before July 2018, all other information about other ARBs is irrelevant.

a. A similar chemical structure does not establish the relevance of, or justify discovery into, the full manufacturing process and all testing procedures for those drugs.

Although Plaintiffs "need not prove [their] case on the merits in order to obtain disclosure," they "must ... make some threshold showing of relevance before" Defendants are "obligated to open to discovery" a variety of drugs "not directly at issue in the action." *Fine*, 133 F.R.D. at 443 (denying discovery into products not at issue); *Jesberg v. Baxter Healthcare Corp.*, No. 97-1062, 2005 WL 8164570, at *4 (D. Minn. June 24, 2005) (courts require a "threshold showing of relevance ... before parties are required to open wide the doors of discovery and to produce a variety of information which does not reasonably bear upon the issues in the case." (quoting *Hofer*, 981 F.2d at 382)); *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Practices & Prods. Liab. Litig.*, No. 16-2695, 2018 WL 4200315, at *6 (D.N.M. Aug. 31, 2018) (noting that a "modicum of objective support" is a prerequisite to seeking discovery on a particular subject (citation omitted)); *In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.*, No. 13-2419, 2015 WL 13715287, at *2 (D. Mass. Feb. 26, 2015) ("Parties must disclose some relevant factual basis for their claim before requested discovery will be allowed.").

Thus, in *Stone v. Zimmer, Inc.*, the court rejected the plaintiffs' request for data related to all of the defendant's hip replacement product lines. *See* 2010 WL 11602738, at *2 (S.D. Fla. Jan. 7, 2010). The plaintiffs had argued that discovery into the other hip replacement products was warranted "because the testing supporting the FDA's approval was the same for all of the

components manufactured by the Defendant." *Id.* However, absent "any expert analysis" support their claim that the hip replacement products "share[d] the *pertinent characteristics* that led to" the plaintiffs' injuries, the court found the plaintiffs' "generalized comparisons" to be "insufficient to warrant discovery of Defendant's entire line of products in its ZMR hip replacement system." *Id.* (emphasis added, citations omitted).

As in *Stone*, Plaintiffs here have not made the requisite "threshold evidentiary showing" to demonstrate the relevance of the broad discovery they seek related to other ARBs. Instead, they merely state that several ARBs share a single chemical feature, and then speculate that information related to the entire manufacturing processes for these drugs is somehow relevant. *See* Dkt. 289 at 289. But the FDA's investigation has shown that valsartan, losartan, irbesartan, olmesartan, and candesartan are *not* similar simply because they contain a tetrazole ring. As Plaintiffs recognize, the FDA has investigated all ARBs for potential nitrosamine contamination. These investigations have not resulted in recalls of every drug. In fact, not a single batch of olmesartan or candesartan has been recalled by *a single* Defendant. Several Defendants have not recalled any ARB drug other than valsartan.[14]

Plaintiffs have pointed to nothing to indicate that the manufacturing process for either of those drugs poses an actual—rather than a speculative—risk of nitrosamine formation. And there is no reason to believe that anything about olmesartan or candesartan, or any other drug that a particular Defendant has not recalled, would have put Defendants on notice of the potential risk of NDMA or NDEA as a byproduct of the valsartan API manufacturing process. Therefore, discovery into these other drugs should be denied. *See Fasset v. Sears Holdings Corp.*, 319 F.R.D. 143, 153 (M.D. Pa. 2017) (denying discovery into products not at issue because plaintiffs had "not met their burden" of showing relevance); *Stone*, 2010 WL 11602738, at *2-3 (plaintiffs' generalized comparisons between at issue product and other devices were insufficient to warrant discovery of the defendant's entire line of products in its hip replacement system); *Doyle v. Eli Lilly & Co.*, No. 06-412, 2007 WL 2021828, at *5 (D. Neb. July 9, 2007) (denying discovery into antidepressants not at issue because plaintiffs "failed to meet their burden of showing the requested discovery … reasonably b[ore] on the issues in the case"). "Mere speculation that information might be useful will not suffice; litigants seeking … discovery must describe with a reasonable degree of specificity, the information they hope to obtain ***and*** its importance to their case." *Doyle*, 2007 WL 2021828, at *2 (emphasis added).[15]

[14] Mylan has not recalled any ARB drug other than valsartan for potentially containing a nitrosamine.

[15] The posture of these cases, and the detail of the courts' analyses, further demonstrate that allowing any discovery into drugs other than valsartan is entirely inappropriate at this juncture. In most cases, a party seeks discovery into another product as a second phase of discovery. At that point, the parties

Even if Plaintiffs could conjure up some scenario where information relating to other ARBs—including those like candesartan and olmesartan which have never been the subject of recall and will not be implicated by any upcoming order from the JPML—might be relevant, these requests are unduly burdensome and "overly broad on [their] face[.]" *Burleson v. Cooper Tire & Rubber Co.*, 2014 WL 11514677, at *1 (D.N.M. June 12, 2014) (quoting *Bonanno v. Quizno's Franchise Co.*, 255 F.R.D. 550, 553 (D. Colo. 2009)). Indeed, Plaintiffs demand production of information relating to other drugs and to manufacturing processes using recovered or recycled solvents, a request that will likely implicate some Defendants' entire drug portfolio. As in *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, the disproportionate and virtually boundless scope of Plaintiffs' requests would "thwart any attempt at a just, speed, or inexpensive determination of the action." 624 F. Supp. 1212, 1241 (S.D. Ohio 1985).

b. Use of the same solvent does not establish the relevance of, or justify discovery into, the full manufacturing process and all testing procedures for those drugs.

For similar reasons, Plaintiffs have failed to justify their request for discovery into "other manufacturing processes which use the same recycled solvents or catalysts." Dkt. 289 at 16. Plaintiffs *already request* documents related to the solvents used in valsartan, including the source of those solvents, testing on those solvents, and studies on the risk of contamination from those solvents. *See* Dkt. 290–2 at *e.g.* ¶¶ 20, 27, 40. These solvent-specific requests will provide Plaintiffs with all the necessary information about Defendants' knowledge about impure recycled solvents. Especially at this juncture, before Rule 34 discovery has begun, it is premature for the Court to order discovery into areas of borderline relevance that may end up being completely duplicative of the discovery that is sure to proceed into valsartan.

Continuing with their pattern of attempting to justify discovery on all Defendants based on a discrete, defendant-specific issue, Plaintiffs also seek discovery regarding the solvent dimethylformamide ("DMF"), for no other reason than that "[s]ome Defendants [] utilized [it] in their manufacturing processes." Dkt. 289 at 21. And although not a single Plaintiff alleges injury from ingesting DMF, Plaintiffs declare that they are "entitled to discovery" of *every other drug manufacturing process* that used DMF. Dkt. 289 at 22. They do not even attempt to tie DMF to any question relevant to the alleged NDMA or NDEA impurities at issue, and thus the discovery—if permitted—would amount to an improper fishing expedition.[16]

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have already focused in on the key areas of dispute and are able to provide support from experts about *precisely why* certain areas of inquiry into other drugs is relevant and useful.

[16] As Mylan's core discovery production demonstrates, Mylan's valsartan API manufacturing process does not use or incorporate DMF. Thus, as it relates to Mylan, this issue is doubly irrelevant.

c. Relevance, if any, is limited to the narrow topic of potential notice of the risk of NDMA or NDEA formation in another drug with a similar chemical structure to valsartan before July 2018.

Even when courts permit inquiry into products other than the product at issue in litigation, they limit discovery to the particular topics that are likely to reveal relevant information; they do not give litigants *carte blanche* to explore every detail of the other products. In products liability cases, the inquiry is therefore often limited to accidents involving products with similar characteristics or to reports showing similar injuries from substantially similar products. *See, e.g., Uitts v. General Motors Corp.*, 58 F.R.D. 450, 452 (E.D. Pa. 1972) (permitting discovery into similar accidents involving cars that shared "identical equipment"); *Doyle*, 2007 WL 2021828, at *5 (permitting discovery of risk of particular side effect at issue in other drug); *Fassett*, 319 F.R.D. at 153 (noting that "evidence of prior accidents involving the same product under similar circumstances" can be relevant "to show notice to the defendant" but recognizing "the almost universal requirement…that the prior occurrence must involve facts and circumstances which are substantially similar to those involved in the case" (citations omitted)). In short, there is no basis for Plaintiffs' request for unbounded discovery into the "manufacturing processes, solvents, and testing Defendants utilized during the manufacturing of all other sartan drugs." Dkt. 289 at 16. Rather, any such discovery must be narrowly tailored to the potential notice issue.

3. <u>It is premature to allow discovery into drugs other than valsartan.</u>

As the Court is aware, there is currently a motion pending before the Judicial Panel on Multidistrict Litigation to expand this MDL to include losartan and irbesartan as well as other ARBs. If the JPML decides to expand this MDL beyond valsartan, only then will discovery regarding other ARBs become relevant. If that happens, Plaintiffs must serve document requests directed at discovery related to the other ARBs, and Defendants must have an opportunity to carefully consider and, as necessary, object and respond to those requests. Unless and until the JPML decides to expand this MDL, it is premature for the Court to determine the scope of discovery into drugs other than valsartan.

At the very least, the Court should defer its decision on discovery into other drugs until after Plaintiffs have received discovery related to valsartan. Other than a single document request, Plaintiffs do not currently seek any information related to any other drug. From their existing valsartan-specific document requests alone, Plaintiffs will likely receive millions of pages in productions from the many Defendants in these actions. There is no need at this juncture to complicate what promises to be a thorough and detailed discovery process with four times the volume related to drugs that are not alleged to have harmed any present plaintiff within this MDL.

If at some later point Plaintiffs determine that they do, in fact, require information related to other drugs, Plaintiffs should be required to serve additional document requests identifying with particularity each category of documents they seek, as Rule 34(b)(1) requires. With the benefit of valsartan-related discovery, Plaintiffs should be able to serve informed document requests that target discrete areas of inquiry. Defendants should then have the opportunity to assess the true scope of

Plaintiffs' requests and to raise appropriate objections. The Court, too, will benefit from the valsartan-related discovery, and be in a better position to assess the proportionality factors enumerated in Rule 26(b)(1). *See* Manual of Complex Litigation, Fourth § 11.422 at 54–55 ("For effective discovery control, initial discovery should focus on matters … that appear pivotal."); The Sedona Conference, *Commentary on Proportionality in Electronic Discovery*, 18 Sedona Conf. J. 141, 157 (2017) ([T]he court … may find it appropriate to conduct discovery in phases, starting with discovery of clearly relevant information available from the most accessible and least expensive sources.").

D. Litigation holds are privileged and should not be produced.

Litigation holds are not discoverable in the absence of evidence of spoliation, which does not exist here. Plaintiffs make the unsubstantiated claim that "the [litigation] notice itself, as well as the dates, distribution lists, and preservation instructions in a litigation hold, cannot be shielded from discovery." Dkt. 289 at 24-25. But, as this Court has held, in general, "litigation hold letters are not discoverable[.]" *Major Tours, Inc. v. Colorel*, No. 05-3091, 2009 WL 2413631, at *2 (D.N.J. Aug. 4, 2009)[17]; *see also Pearlstein v. BlackBerry Ltd.*, No. 13-7060, 2019 WL 1259382, at *19 (S.D.N.Y. Mar. 19, 2019) (denying plaintiffs' motion to compel and finding that litigation hold notice was privileged); *Greenberger v. Internal Revenue Serv.*, 283 F. Supp. 3d 1354, 1373 n. 15 (N.D. Ga. 2017) (finding that "litigation hold letters are generally privileged" and that the defendant "was entitled to (and did) withhold it on that basis."); *Gibson*, 510 F. Supp. 2d at 1123 (finding litigation hold letters not discoverable and cautioning that compelling their disclosure "could dissuade other businesses from issuing such instructions in the event of litigation."). And any attempt to differentiate between the actual litigation holds and the dates, distribution lists, and preservation instructions would be a distinction without a difference; there would be no point in protecting the litigation holds if the very same information could be turned over in piecemeal fashion.

Only when spoliation occurs do litigation hold letters become discoverable. *See, e.g., Major Tours*, 2009 WL 2413631, at *2 (adopting the "prevailing view" and collecting cases). Spoliation "is the destruction or significant alteration of evidence, or the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation." *Id*. (citation omitted). Under Third Circuit precedent,"[s]poliation occurs where: the evidence was in the party's control; the evidence is relevant to the claims or defenses in the case; there has been actual suppression or

[17] Plaintiffs attempt to distinguish *Major Tours* by claiming that "the issue here is different." Dkt. 289 at 26. But the plaintiffs in *Major Tours* made the same argument that Plaintiffs make here—that the litigation hold "letters are relevant to their examination of the scope of defendants' document production and whether they spoliated relevant evidence." *Major Tours*, 2009 WL 2413631, at *1. The only difference between *Major Tours* and this litigation is that the plaintiffs in *Major Tours* made a preliminary showing of spoliation, whereas here, for the reasons discussed below, Plaintiffs have not.

withholding of evidence; and the duty to preserve the evidence was reasonably foreseeable to the party." *Bull v. United Parcel Serv., Inc.*, 665 F.3d 68, 73 (3d Cir. 2012); *see also Brewer v. Quaker State Oil Refining Corp.*, 72 F.3d 326, 334 (3d Cir. 1995). In the voluminous documents that have been produced, there is absolutely no suggestion that any Defendants spoliated evidence that related to nitrosamine contamination in their valsartan at a time when they were required to preserve evidence related to this case. Plaintiffs' arguments to the contrary—explored below—only serve to highlight this reality.

To begin with, the two MDLs referenced by Plaintiffs are simply inapplicable. First, as Plaintiffs admit, the litigation hold notice from *In re Benicar (Olmesartan) Prods. Liability Litigation* referenced in Plaintiffs' letter brief was produced voluntarily. *See id*. at 26-26; Ex. 29. Second, Plaintiffs' citation to the pretrial order from *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation*, *see* Dkt. 289 at 26, to support the assertion that "[l]itigation holds have been produced in other MDL litigations as well[,]" misses the mark. *See* 299 F.R.D. 502 (S.D.W.V. 2014). First of all, the *In re Ethicon* court—in the cited order—walked through a comprehensive history of document mismanagement and anemic production by the defendant, ultimately finding that the plaintiffs had "substantially succeeded" in showing spoliation. *See id*. at 509–11; 526. This fact alone renders the order inapplicable, as Plaintiffs in this case have not demonstrated that any Defendant has engaged in any form of spoliation whatsoever. Moreover, although the *In re Ethicon* order suggests that certain litigation hold notices were, at some point, produced, described, or otherwise made available to the court—voluntarily or involuntarily—the order does not describe how or why. *See id*. at 508–10. Critically, the protection or production of litigation hold notices was not at issue in the *In re Ethicon* order cited by Plaintiffs, and the opinion contained no discussion of whether and under what circumstances such notices should be discoverable. *See id*., *passim*. Thus, the *In re Ethicon* order is entirely irrelevant to issue of discoverability of litigation hold notices.

As for the facts in *this* case, Plaintiffs cite to two "examples" of "potential spoliation"[18] to argue for the discoverability of the hold letters: namely a 2016 inspection report issued to Hetero Labs Limited that discusses observations of document shredding and a 2017 warning letter issued to Mylan's Nashik facility which discusses missing data.[19] Putting aside the obvious fact that

[18] Plaintiffs' use of the words "potential spoliation" aptly illustrate their lack of evidence to make even a preliminary showing of the existence of spoliation by any Defendant.

[19] Mylan's Nashik facility is a finished-dose facility, not an API facility, and, therefore, has nothing to do with the issues involved in this litigation. Plaintiffs' Master Complaints make clear that their theory of the case is that the impurities were introduced during a particular and specific step in the API manufacturing process. This fact alone takes this so-called "evidence" an additional step further away from relevance. What's more, the Nashik warning letter didn't even mention valsartan or the potential presence of nitrosamines (or any other carcinogen, for that matter). Finally, in response to the warning letter, Mylan retained an independent consultant who confirmed that *no chromatograms, data, or results had actually been deleted*. As such, the Nashik warning letter

Plaintiffs will not be able to satisfy the four *Bull* factors, a government inspection or investigation does not give rise to a duty to preserve documents for a private lawsuit brought after the fact of the government inspection/investigation. *See In re Delta/AirTran Baggage Fee Antitrust Litig.*, 770 F. Supp. 2d 1299 (N.D. Ga. 2011). There, the plaintiffs—private parties in civil litigation—argued that a Civil Investigative Demand ("CID") issued by the Department of Justice triggered a duty on the part of Delta to preserve documents for the plaintiffs who brought suit three months after the CID was issued. The court flatly rejected such an argument as nonsensical:

> In essence, Plaintiffs ask this Court to hold that, as a matter of law, when a business is served with a CID, an irrebuttable presumption arises that civil litigation filed by one or more parties against the business receiving the CID is reasonably foreseeable. No court has so held, and this Court is unwilling to be the first. […] Consequently, Delta owed no preservation duty to Plaintiffs that it could have breached. If Delta failed to comply with the CID, the DOJ—not Plaintiffs—is the appropriate party to take action.

Id. at 1308–09. The court in *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, a multidistrict litigation involving prescription drugs, reached the same result. *See* No. 16-2734, 2018 WL 4856767, at *5 (N.D. Fla. Oct. 5, 2018) (relying in part on *In re Delta/AirTran Baggage Fee Antitrust Litig*. and concluding that the defendant's "duty to preserve evidence, if any, applied to the DOJ and the claims in that case involving off-label promotion and does not apply...to Plaintiffs in [this] case"). Thus, if a CID—a clear signal that the DOJ is conducting an investigation with an eye toward civil or criminal litigation—does not give rise to a duty to preserve documents for hypothetical plaintiffs in a potential future MDL, it simply cannot be the case that an FDA inspection would trigger such an obligation.

Simply put, "[i]f the duty to preserve evidence 'has not been triggered at the time the evidence was destroyed, then there can be no spoliation.'" *Antoine v. KPMG Corp.*, No. 08-6415, 2010 WL 147928, at *10 (D.N.J. Jan. 6, 2010) (quoting *Kounelis v. Sherrer*, 529 F. Supp. 2d 503, 518 (D.N.J. 2008)). Therefore, even if Plaintiffs' anecdotes were true, there could have been no spoliation because Defendants were not under a duty to preserve evidence at the time of those alleged events.

As this Court has stated, "litigation hold letters should be produced if there has been a preliminary showing of spoliation." *Major Tours*, 2009 WL 2413631, at *5. Plaintiffs have not shown and cannot show that Defendants suppressed or destroyed documents they had a duty to preserve in relation to the valsartan investigation and recall or this litigation. Therefore, Plaintiffs' request that the litigation holds be subject to discovery fails.

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flaunted by Plaintiffs as supposed "evidence" of "potential spoliation" is, in reality, nothing more than a red herring.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

SAG
Enclosures

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